

Food and Drug Administration Rockville MD 20857

STATEMENT OF AUTHORITY AND CONFIDENTIALITY COMMITMENT

FROM

THE UNITED STATES FOOD AND DRUG ADMINISTRATION OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED

\mathbf{BY}

THE AUSTRALIAN PESTICIDES AND VETERINARY MEDICINES AUTHORITY

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is authorized to disclose non-public information to the United States Food and Drug Administration of the Department of Health and Human Services (USFDA) regarding APVMA-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

USFDA understands that some of the information it receives from APVMA may include non-public information exempt from public disclosure under the laws and regulations of Australia, such as confidential commercial information; trade secret information; personal privacy information, law enforcement information; or internal, pre-decisional information. USFDA understands that this non-public information is shared in confidence, and that APVMA considers it critical that USFDA maintains the confidentiality of the information. Public disclosure of this information by USFDA could seriously jeopardize any further scientific and regulatory interactions between APVMA and USFDA. APVMA will advise USFDA of the non-public status of the information at the time that the information is shared.

Therefore, USFDA certifies that it:

- 1. has the authority to protect from public disclosure the non-public information provided to USFDA in confidence by APVMA;
- 2. will not publicly disclose the APVMA-provided non-public information without the written authorization of the owner of the information, the written authorization from the individual who is the subject of the personal privacy information, or a written statement from APVMA that the information no longer has non-public status;

- 3. will inform APVMA within two working days of any effort made by judicial or legislative mandate to obtain APVMA-provided non-public information from USFDA. If such judicial or legislative mandate orders disclosure of APVMA-provided non-public information, USFDA will take all appropriate legal measures in an effort to ensure that the information will be disclosed in a manner that protects the information from public disclosure; and
- 4. will promptly inform APVMA of any changes to USFDA's laws, or to any relevant policies or procedures, that would affect USFDA's ability to honor the commitments in this document.

Lester M. Crawford, D.V.M., Ph.D.

Commissioner of Food and Drugs
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